

<b>Notice of Allowability</b>	Application No.	Applicant(s)
	09/840,008	EVANS, RONALD M.
	Examiner Joseph T. Woitach	Art Unit 1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to July 22, 2004.
2.  The allowed claim(s) is/are 1-26.
3.  The drawings filed on 29 April 2003 are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\*
  - c)  None
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application (PTO-152)
6.  Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

### **DETAILED ACTION**

This application filed April 20, 2001 is a continuation in part of 09/458,366, filed December 9, 1999, which is a continuation in part of 09/227,718, filed January 8, 1999, which is a continuation in part of 09/005,286, filed January 9, 1998.

Applicants' amendment filed July 22, 2004, has been received and entered. Claims 1-26 are pending.

#### ***Election/Restrictions***

The elected invention has been found allowable, and a review and examination of the linking claims for the full breadth to the claimed invention has also been found allowable. Accordingly, groups I and II are rejoined, and the restriction requirement is withdrawn.

#### ***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance:

As noted previously, the claimed invention is free of the art of record. The claimed invention is based on the discovery and characterization of a new class of steroid receptors and their consensus sequence in the promoter element. Examiner agrees that the claims have been amended to recite and encompass elements of the disclosed invention addressing the issues raised under 35 USC 112, first paragraph. With respect to the obvious double patenting rejection, upon review of the pending claims of '268, Examiner agrees that the two inventions are distinct and not obvious over one another in that they contain materially and structurally

different elements. With respect to the withdrawal of the restriction requirement, it is noted that only difference between the two groups is the nuclear receptor recited in the dependent claims, the steroid xenobiotic receptor and the pregnane X receptor. Each is fully disclosed in the present specification, and demonstrated to be effective in the expression system as instantly claimed. Given the characterization of these specific receptors, the similarity of the essential elements of the two receptors, and the limitations of the promoter element used in the expression system, the claims meet all the requirements of 35 USC 112, first paragraph.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

JOSEPH WOITACH  
PATENT EXAMINER

*Joe Woitach*  
AU1632